EXHIBIT 17

DRAFT

THE COMPLICATED HISTORY OF MEDICAID REGULATIONS ON DRUG REIMBURSEMENT

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Dealing with the proper policy towards prescription drug reimbursement has been one of the most perplexing and time-consuming regulatory efforts that the Department of Health and Human Services has undertaken in recent years. Although the major impetus for regulation in this area has been Federal budget savings, the amounts involved are relatively small compared to initiatives in other areas such as hospital reimbursement. The time and attention we have spent on this issue have been greatly disproportionate to the direct Federal budgetary stake.

I think that this time has been well spent, however, given the complex effects of Federal policy in this area. Drug reimbursement policy affects the financial health of tens of thousands of small businessmen, intervenes in a highly competitive market (a rarity in the health care industry), intrudes on the physician/pharmacist/patient relationship, affects the economics of pharmaceutical research and manufacturing, and sets the terms for the administration of one-half of all the claims paid under the Medicaid program. In addition to these direct effects, Federal rules can, and to some extent have, provided a "model" which private insurers follow.

As you know, the first major Federal regulation of drug reimbursement was put in place in 1975: the "MAC/EAC" program. This regulation was a high priority of then HEW Secretary "Cap the Knife" Weinberger. It was issued during a time of ferment over repeal of state anti-substitution laws, and represented a

major Federal endorsement of the therapeutic value of generic versions of off-patent drugs. Little attention was paid to several highly unusual features of the regulation: its highly detailed requirements for state reimbursement (far more prescriptive than in any other regulation regarding Medicaid payment), and its use of an administered price system based on wholesale costs.

High hopes were held for the 1975 regulation. It was expected to save about $50 million a year (over $100 million in today's dollars) through generic substitution.

The reality was somewhat different. Several years ago HCFA estimated that total multi-source savings were on the order of $10 million a year, about 10% of the original goal. At least one study estimated that savings for single-source drugs under the EAC program were so small that they were probably equaled by the administrative costs.

And, many have argued, the MAC/EAC program imposed hidden costs which far outweighed its nominal benefits. Everyone agrees now that the MAC process itself was all but unworkable. Those of you who opposed the program may not have viewed this as a bad thing, but the observed result was clear.

In the face of widespread complaints from the pharmacy community, in 1982 former Secretary Schweiker appointed a Task Force to

review the situation. I had the dubious honor of chairing that group. We held several hearings at which some of you testified, and found that the only unanimous sentiment was dislike of the existing regulation. Some of the problems we identified were:

- o the clear unworkability of the MAC process;
- o arbitrary and unfair results, such as the use of very low generic prices for products which were not in fact widely available at those prices;
- o disruption of regular purchasing channels; and
- o artificiality of both Red Book prices for some products and dispensing fee surveys.

I have brought with me a "Far Side" cartoon which I think illustrates both the situation we faced and some of the choices we subsequently considered in seeking to design reforms. [copies on the tables, or to pass out]

The Task Force identified and recommended a series of relatively minor reforms which could be implemented, including abolition of an internal HHS Pharmaceutical Reimbursement Board and placing responsibility within the Health Care Financing Administration, and replacing a cumbersome public hearing process on each drug with a more streamlined approach. We did not, however, recommend

DRUG PAYMENT OPTIONS

"Okay, okay, okay... Everyone just calm down and we'll try this thing one more time."

tampering with the basic structure of the regulation. We duly presented these recommendations to then-Secretary Heckler.

Over the next two years, several things ocurred which had a significant effect on subsequent events:

- o many states created or expanded so-called "mini-MAC" programs to cover more multi-source drugs (HHS had placed a hold on new MAC limits pending implementation of Task Force Reforms);

- o after many years of impasse, the Congress passed the "Drug Price Competition and Patent Term Restoration Act" which greatly eased the entry of generic competitors to a large number of post-1962 drugs coming off patent, including such heavyweights as Valium;

- o the Inspector General of HHS issued a report claiming that published wholesale prices were on average about 16% higher than prices actually paid, and that upwards of $50 million a year in single-source savings could be obtained. This report was followed by a sporadic effort to encourage states to create a new set of surveys covering wholesale prices, and a crescendo of complaints over both the validity of the IG estimates (the report exaggerated somewhat the discrepancies in prices) and its failure to recognize that many states had deliberately held down dispensing fees as a

quid pro quo for known "fat" in published wholesale prices; and

o the Congress entered the dispute for the first time, reflecting concern over a substantial rise in drug prices after many years of below-inflation increases. Again, I had the dubious honor of sitting in a key chair; this time in front of Chairman Waxman.

These events not only delayed implementation of the Task Force reforms but led us to consider further whether more fundamental reforms should be made. This deliberation was aided by two internal HHS developments:

o staff developed the "PhIP" concept, a super-simplified method of encouraging substitution. PhIP's "150% of the lowest priced generic wholesale price, plus dispensing fee" had two major economic implications--the possibility of extra profits for pharmacists who sought out the lowest-priced generic and, as a result, potentially substantial effects on the pricing and manufacturing of generics themselves; and,

o in partial response to the problems and vistas opened up by the PhIP idea, which circulated informally for months, discussions with retail pharmacy representatives led staff to develop another and even more radical "CIP" idea--

reimbursement of both single- and multiple-source drugs based primarily on retail prices, with total elimination of the EAC system. The essence of the CIP proposal was to take advantage of competitive market forces which clearly dominated the sale of pharmaceutical products.

During this period, and the subsequent rule-making, we were ever cognizant of other complications:

o the Medicaid statute requires that covered services be readily available to clients. For drugs, neighborhood access and hence participation by the majority of pharmacists is therefore most important;

o Medicaid is a cooperative Federal-State program. By law and tradition, states have great flexibility in choosing what services to cover and how to pay for them. MAC/EAC is a "limits" regulation and all other regulations of this type give states great discretion provided that overall spending is constrained;

o The pharmacy community has many diverse interests, some similar but some potentially conflicting. Obviously, predominantly research-oriented firms do not have the same perspective on substitution as predominantly generic houses. Similarly, policies can affect chain and independent pharmacies quite differently, reflecting the somewhat

different cost structure and services of different types of store; and

o administerability--the states and the pharmacies have a great deal of time, money, and expertise committed to the MAC/EAC system. Major changes could be most disruptive and require years to implement.

In the event, we promulgated a proposed rule in the summer of 1986. This rule advanced three major options--MAC reform, PhIP, and CIP--and under each option our intention to increase state flexibility. Before and during the rule-making process we consulted extensively with all of the major affected interests, prepared internal analyses and studies, and went through a thorough process of analyzing options. We sought and got Department of Justice (antitrust division) and FTC comments as well.

While I don't want to get into all the nuances of these comments and what we learned, it is fair to say that two things were clear: no one option commanded the endorsement of all the key interests, and every option had significant problems. CIP, for example, was in one form or another endorsed by everybody but the states; however, the agreement in principle did not extend to the actual details of implementation.

One additional complicating factor arose because the Office of

Management and Budget for the first time evidenced an interest in the subject. The OMB perspective is first and foremost budgetary, but OMB also has substantial interest in both regulatory reform and federalism. Regardless, OMB pressed us for an early and budget-saving final rule.

As you know, the final rule we published this summer surprised many. The basic reform it advanced was in one respect fairly radical: we chose to abolish all requirements for a particular payment method, leaving this up to the states. This primarily reflected the inconsistency of the old rule with the state flexibility premise of the Medicaid program, problems we identified in all the options we had advanced, and our growing realization that while we didn't like MAC/EAC, we didn't have a clearly superior alternative. Actually, this should not have been a surprise because we had originally proposed to give the states much greater flexibility regardless of preferred option.

As a second big reform, we did impose overall aggregate spending limits. Unlike MAC/EAC these limits were not set drug-by-drug but on an overall basis. Figuring out how to do this was the hardest part of the decision because we didn't want those limits to dictate a payment method, and did want them to be workable. For multiple-source drugs we finally chose something that vaguely resembles the PhIP proposal, primarily because it was equally or even more simple to measure compliance as an aggregate limit as on a drug-by-drug basis. However, and I want to emphasize this,

nothing in the final rule requires or even encourages states to pick the lowest price generic as the basis for reimbursement for particular drugs. In fact, the limit we adopted provides maneuver room for a great variety of reimbursement approaches. The only thing we insist on is that as prudent purchasers we will not reimburse states the full amount of leading brand prices for drugs with multiple and lower-priced competitors evaluated by FDA as therapeutically eqivalent. This, of course, was no surprise at all and had been assumed in the original Task Force report and all subsequent proposals.

For single-source drugs the problem of setting an aggregate limit was harder. The basic problem is that we had no simple metric. Whatever the virtues of competitive market prices, they don't appear neatly printed in a Red Book or Blue Book. Hence, if we were to use competitive prices as an aggregate limit states might have had to initiate new data collection scarcely different from the steps required to implement the CIP option. After considerable back and forth within the Department and with OMB, we finally decided to benchmark the aggregate limit against what the states would spend if they used the EAC approach. This at least had the virtue of a familiar baseline.

In one respect I am disappointed with the final rule. I would have liked to see a ringing endorsement of a healthy, competitive market. One the other hand, we did lift a series of unnecessary impediments to efficient and effective drug reimbursement and

went farther than would have been deemed likely several years ago.

There is also an important point about reality. Regardless of what we decided--even if we had selected CIP as the preferred payment method--the great majority of the states would have continued to administer "mini-MACs" and an EAC-like system. The states' preferred practices work, save money, and can be fine-tuned to reflect local conditions. Bureaucratic inertia is a powerful force and we never sought to impose a new system against the states' desires. Realistically, much of the debate was over symbolism, not over what was going to happen in the real world.

Indeed, as several PMA companies argued during the public comment process, we were going to achieve big savings from generic substititution even if we had no rule at all, simply because of the product competition which is occurring right now and foreseeable over the next few years. Viewed in this light, our final rule does not create brand new constraints, but is simply an outer envelope guaranteeing that the public treasury will benefit from market forces.